Docket No.: AM 101333
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Wumin Li et al.

Application No.: 10/796,925 Confirmation No.: 3270

Filed: March 10, 2004 Art Unit: 1645

For: ADJUVANTED BOVINE VACCINES Examiner: Lakia J. Tongue

AMENDED APPEAL BRIEF UNDER 37 CFR 41.37(d)

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Amended Appeal Brief is submitted in response to the Notification of Non-Compliant Appeal Brief (37 CFR 41.37) ("the Notice") received in connection with the above-identified application that was mailed on November 18, 2009. The Notice advises that the Appeal Brief that was filed on November 2, 2009 was defective because the argument section (i.e., Section VII that begins on page 7) did not present an argument under a separate heading for each ground of rejection on appeal.

This Amended Appeal Brief amends Section VII to include a separate heading for both grounds of rejection that set forth in Section VI. The basis for finding the Appeal Brief non-compliant is thus believed to be addressed and overcome. Pursuant to the Notice, only an amended version of Section VII is submitted herewith.

It is requested that the Appeal Brief be amended by replacing Section VII of the Appeal Brief that was found to be defective with the present, corrected version of Section VII.

Consideration of Appellant's Appeal Brief, as amended by the present paper, is respectfully requested.

No fee is believed due. The Commissioner is authorized to charge any fee determined to be due and credit any overpayments to account no. 04-0100.

VII. ARGUMENT

(1) RESPONSE TO GROUND 1: CLAIMS 22 AND 24 ARE PATENTABLE UNDER 35 U.S.C. 103(A) OVER JOHNSON IN VIEW OF SAITO AND BAYLOR

A. BACKGROUND

The claims on appeal are directed to a method for reducing shedding of *E. coli* strain O157:H7 in an animal by parenterally injecting a vaccine composition comprising inactivated or killed whole *E. coli* O157:H7, an adjuvant having the composition set out in claim 22, and aluminum hydroxide. *See* claim 22. The application discloses that *E. coli* O157:H7 is a bacterium that colonizes the gut of bovine species (among other species) and is a human pathogen that infects humans, primarily through ingestion of contaminated beef. Specification at page 1, lines 11-19. An important route of *E. coli* O157:H7 contamination of beef is the shedding of *E. coli* O157:H7 into the feces of colonized animals, subsequent contamination of beef during processing and slaughtering, and ingestion of contaminated beef. *Id.* and page 2, lines 1-9. Various methods have been attempted to reduce the level of *E. coli* O157:H7 contamination, including by immunizing animals to prevent *E. coli* O157:H7 shedding. *Id.* at 3-6.

According to the specification, "it remains a challenge to produce a vaccine to effectively prevent *E. coli* O157:H7 colonizations in ruminant animals, particularly bovines, that can be passed through their carcasses into the human food supply." Specification at page 2, lines 31-33. Such challenges include the problem that a live bacterial vaccine may potentially be unsafe, whereas a killed or inactivated vaccine may fail to stimulate an effective immunologic response and that adjuvants used to stimulate an immunological response may have undesirable consequences. Specification at page 3, lines 25-30. Additionally, because the beef of vaccinated animals is ultimately sold to consumers, "it is highly desirable to minimize injection site reactions which adversely impact the meat quality of an animal which is sold for food consumption." Specification at page 3, line 33 though page 4, line 2.

Appellants' claimed invention addresses the problem of providing effective vaccination of animals that reduces shedding of *E. coli* O157:H7 in colonized animals without adversely affecting meat quality by providing for vaccinating animals with a combination of dead or attenuated *E. coli* O157:H7, the adjuvant recited in claim 22, and aluminum hydroxide. Example 2 of the specification and a Declaration of Under 37 C.F.R. §1.132 from co-inventor Wumin Li ("the Li Declaration," attached in Evidence Appendix B) set out a comparison of a vaccine according to the claimed invention and a vaccine formulated with the adjuvant, aluminum hydroxide.[1] The results set out in Example 2 and the Li Declaration demonstrate that a vaccine according to the invention comprising the SP oil adjuvant and aluminum hydroxide results in a significantly higher immune response, compared to aluminum hydroxide alone but with similar rates of injection site reactions. The Li Declaration sets out that it was unexpected that the claimed composition of a metabolizable oil (i.e., SP Oil) plus aluminum hydroxide had a significant improvement in titers versus the standard adjuvant (aluminum hydroxide) and, additionally, that it was unexpected that the size of the reaction lump at the site of injection was the same for aluminum hydroxide alone and for the vaccine according to the invention that had such a significantly higher titer. Appendix B, Li Declaration at page 5.

Example 3 of the specification describes a field study performed to compare the effectiveness of various interventions to reduce the prevalence of *E. coli* in feedlot cattle. The results of the study showed that a vaccine according to the invention reduced *E. coli* O157 prevalence by 20.3% on hide samples and by 31.1% in fecal samples and that, when combined with other intervention strategies, e.g., *L. acidophilis* or neomycin feed supplement, the vaccine provided additional reduction in antigen shedding.

The Examiner asserts that claims 22 and 24 are obvious over Johnson in view of Saito and Baylor "because all the claimed elements were known to in the prior art and one skilled in the art could have combined the elements as claimed with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the

[1] Example 2 of the specification is written in the present tense and is thus a prophetic example. The Li Declaration, is written in the past tense and thus describes work as it was performed and results that were obtained. Notwithstanding that Example 2 is a prophetic example and the Li Declaration reports on a study that was conducted, Example 2 and the Li Declaration set out identical methods and "results." Thus, notwithstanding that Example 2 is set out in prophetic terms and the Li Declaration reports on work that was performed and results obtained, the respective disclosures of Example 2 and the Li Declaration are believed to be the same, and are thus interchangeable.

time of the invention." *See*, e.g., Final Office Action mailed January 7, 2009 at page 8, second paragraph. The Examiner also asserts that the Li Declaration is not persuasive because the claims are drawn to a combination of SP and aluminum hydroxide, whereas "the Li declaration compares their adjuvant to aluminum hydroxide, which is insufficient because the adjuvant compared in the declaration is vastly different than metabolizable oil adjuvants or 'SP Oil' as claimed." Final Office Action mailed January 7, 2009 at page 3-4, bridging paragraph.

The rejection of claims 22 and 24 over Johnson in view of Saito and Baylor should be withdrawn because the Examiner has committed the following errors:

(i) The Examiner has culled selective teachings from the prior art and thus failed to properly ascertain the scope and content of the prior art;

(ii) The Examiner has improperly failed to give weight to the Li Declaration because she has required that a comparison between the claims and Applicants' invention, rather than the prior art.

B. LEGAL PRINCIPLES

"During examination, the examiner bears the initial burden of establishing a prima facie case of obviousness." *In re Kumar,* 418 F.3d 1361, 1366 (Fed. Cir. 2005). In so doing, the Examiner must make the factual determinations set forth in *Graham v. John Deere Co.,* 383 U.S. 1, 17 (1966): (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness, if any. "Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." *In re Rijckaert,* 9 F.3d 1531, 1532 (Fed. Cir. 1993) (citations omitted). Claims are likely to be unobvious "when the prior art teaches away" from their practice. *KSR Int'l. Co. v. Teleflex Inc.,* 550 U.S. 398, 416 (2007). Evidence rebutting a *prima facie* case of obviousness must be considered. *In re Sullivan*, 498 F.3d 1345, 1351 (Fed. Cir. 2007).

C. ANALYSIS

1. The Examiner Has Failed to Properly Consider the Scope and Content of the Prior Art and Differences Between the Prior Art and the Claimed Invention

a. The Examiner misinterprets Johnson and fails to properly ascertain the differences between Johnson and the claimed invention

The Examiner first errs by failing to consider Johnson as a whole. Johnson discloses vaccination of newly weaned dairy calves by intramuscular injection of inactivated *E. coli* O157:H7 bacterin, supplemented with inactivated verotoxin 2 (VT2) and adherence factor, $intimin_{O157}$. Control and experimental animals were treated and then challenged with antibiotic resistant inactivated *E. coli* O157:H7. Johnson reports that shedding of *E. coli* O157:H7 bacteria in feces fell in both vaccinated and control animals within 2-3 weeks of challenge. Johnson discloses that the results obtained "indicate that infection of naturally-reared weaned dairy calves by *E. coli* O157:H7 is frequently transient…and is unlikely to be controlled by immune responses induced by parenterally administered inactivated bacterins."

The Examiner characterizes Johnson by describing the results as set forth above and then concluding, "Johnson et al. does not specifically disclose an adjuvant comprising SP Oil and aluminum hydroxide." *See*, e.g., Final Office Action dated January 7, 2009 at page 7, first two full paragraphs and Non-Final Office Action dated September 16, 2008 at page 6, bottom through page 7, first full paragraph. The Examiner's clipped characterization of Johnson does not completely nor fairly ascertain the scope and content of Johnson, nor the differences between Johnson and the claimed invention. Thus, implicit in the Examiner's characterization is that Johnson discloses an "effective amount" of a vaccine composition for "reducing shedding of *E. coli* O157:H7 in an animal," as recited in claim 1. Such implicit characterization is not correct. Johnson discloses explicitly that there was "little difference" in levels and duration of shedding in vaccinated versus control animals. Johnson thus fails to disclose an "effective amount" of a vaccine for reducing shedding of *E. coli* O157:H7.

The Examiner's consideration of Johnson, moreover, fails to address Johnson's explicit statement that infection of naturally-weaned dairy calves by *E. coli* O157:H7 "is unlikely to be controlled by immune responses induced by parenterally administered inactivated bacterins."

b. The Examiner fails to consider disclosure in Baylor that is inconsistent with the claimed invention

The Examiner has a similarly selective reading of Baylor. The Examiner states that, "Baylor et al., was used solely as an evidentiary reference to demonstrate that aluminum hydroxide has been commonly used as an adjuvant in many vaccines for decades and have [sic] been proven safe." *See,* e.g., Final Office Action mailed January 7, 2009 at pages 6-7, bridging paragraph. Baylor teaches, however, that aluminum adjuvants "have been associated with severe local reactions such as erythema, subcutaneous nodules and contact hypersensitivity." Baylor at Abstract and page S20, column 2, lines 1-4. As set out in the instant specification and discussed above, site reactions, such subcutaneous nodules, adversely affect meat quality and are thus to be minimized. The Examiner, however, takes no notice of Baylor's explicit teaching that aluminum adjuvants are known to be associated with such "severe local reactions."

c. The Examiner mischaracterizes Saito and fails to consider Saito has a whole

The Examiner similarly errs by both mischaracterizing Saito and failing to consider Saito as a whole. The Examiner first mischaracterizes Saito as disclosing "using aluminum hydroxide in the disclosed composition (see paragraphs 0101 and 0109)." *See,* e.g., Final Office Action dated January 7, 2009 at page 6. This statement is not correct. Saito does not disclose a combination of aluminum hydroxide and the water-in-oil-in-water (W/O/W) adjuvants that are the subject of Saito's invention. Saito only mentions aluminum hydroxide in the context of being used by itself in comparative control vaccine compositions. Saito never states or suggests that aluminum hydroxide could or should be used in such W/O/W adjuvants. *See* Amendment filed October 14, 2008 at page 3, bottom paragraph through page 4, second full paragraph.

The Examiner, moreover, refuses to consider portions of Saito that would have discouraged a person of ordinary skill in the art from using aluminum hydroxide in an oil emulsion vaccine composition. Table 6 of Saito, for example, compares the "effectiveness" of various Er formulations (expressed in terms of PD_{50}). An aluminum gel-adjuvanted formulation produced a PD_{50} of 77.1, whereas experimental oil emulsion vaccines produced PD_{50} values as high as 2660.1 (*see* "Vaccine 1"). Similarly, in the Mycoplasma experiments summarized in Table 8, the aluminum hydroxide-adjuvanted formulations performed much worse than the W/O/W formulations as measured by lesion score and percent decrease in lesions. According to Saito, "the aluminum gel vaccine did not at all show a lesion-decreasing effect by the vaccine, irrespective of the presence or

absence of PEG addition." *See* paragraph [0112], last sentence. A skilled person having knowledge of the dismal performance of the aluminum hydroxide gel as an adjuvant, as reported by Saito, would have been highly discouraged from using aluminum hydroxide in combination win an oil emulsion vaccine formulation.

d. In failing to consider the prior art as a whole, the Examiner ignores or fails to give weight to disclosure that that teaches away from the claimed invention and fails to acknowledge the differences between the prior art and the claimed invention

The Examiner's failure to consider the complete content of Johnson, Saito and Baylor is legal error. A prior art reference must be considered as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550 (Fed. Cir. 1983); *In re Hedges,* 783 F.2d 1038, 1041 (Fed. Cir. 1986) ("[T]he prior art as a whole must be considered. The teachings are to be viewed as they would have been viewed by one of ordinary skill."). It is thus, "impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.'" *Id.* (*quoting In re Wesslau,* 353 F.2d 238, 241 (CCPA 1965)). The Examiner has, in particular, failed to consider content in Johnson, Saito and Baylor that teach away from the claimed invention. *In re Kahn,* 441 F. 3d 977, 990 (Fed. Cir. 2006), *quoting In re Gurley,* 27 F.3d 551, 553 (Fed. Cir. 1994). ("A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.") In the absence of considering the portions of the prior art that would discourage one of ordinary skill in the art to make the claimed invention, the Examiner cannot properly conclude the claims are *prima facie* obvious over the prior art.

The Examiner's failure to appreciate or acknowledge that Johnson fails to disclose any reduction in the shedding of *E. coli* O157:H7 following vaccination leads to a failure to fully ascertain the differences between the prior art and the claimed invention. The Examiner thus fails to ascertain that a difference between the prior art and the claimed invention is the administration of an amount of vaccine that is effective in reducing shedding of *E. coli* O157:H7. In the absence of

properly ascertaining the differences between the prior art and the claimed invention, the Examiner cannot properly conclude the claims are *prima facie* obvious over the prior art.

2. The Examiner has improperly failed to give weight to the Li Declaration because she has required a comparison between the claims and Applicants' invention, rather than the prior art

The rejections should also be withdrawn because the Examiner has failed to give proper consideration to the Li Declaration. As set out above, the Li Declaration sets out that is was unexpected that the claimed composition of a metabolizable oil (*i.e.,* SP Oil) plus aluminum hydroxide had a significant improvement in titers versus the standard adjuvant (aluminum hydroxide) and, additionally, that it was unexpected that the size of the reaction lump at the site of injection was the same for aluminum hydroxide alone and for the vaccine according to the invention that had such a significantly higher titer. Appendix B, Li Declaration at page 5. The Examiner failed to give due consideration to the Li Declaration on the grounds that the claims are drawn to a combination of SP and aluminum hydroxide, whereas "the Li declaration compares their [sic] adjuvant to aluminum hydroxide, which is insufficient because the adjuvant compared in the declaration is vastly different than metabolizable oil adjuvants or 'SP Oil' as claimed." Final Office Action mailed January 7, 2009 at page 3-4, bridging paragraph. The Examiner's failure to consider the Li Declaration is legal error because in essence it requires a showing of unexpected results by comparing the claimed invention to itself, rather than the closest prior art.

Unexpected results are shown by comparing the claimed invention to the closest prior art. *Pfizer, Inc. v. Apotex, Inc.,* 480 F.3d 1348, 1370 (Fed. Cir. 2007) (*citing Kao Corp. v. Unilever United States, Inc.,* 441 F.3d 963, 970 (Fed. Cir. 2006) and *In re Baxter Travenol Labs.,* 952 F.2d 388, 392 (Fed. Cir. 1991), *reh'g & reh'g en banc denied,* 488 F.3d 1377, 2007 U.S. App. LEXIS 11886 (Fed. Cir., 2007), *cert denied,* 127 S. Ct. 2967, 2007 U.S. LEXIS 7522 (U.S., 2007). The claimed invention may alternatively be compared to closer prior art than cited by the Examiner. *See* MPEP 716.02(3), references omitted. However, "applicant is not required to compare the claimed invention with subject matter that does not exist in the prior art." *Id., citing in re Geiger,* 815 F.2d 686, 689 (Fed. Cir. 1987) (Newman, J., concurring). Requiring a comparison between the

claimed invention and the combination of references used to reject the claims under section 103 "would be requiring comparison of the invention with the results of the invention." *Id., citing in re Chapman,* 357 F.2d 418, 422 (CCPA 1966).

Here, the claimed invention is a method for reducing shedding of *E. coli* strain O157:H7 in an animal by parenteral administration of an effective amount of a composition comprising inactivated or killed whole *E. coli* O157:H7, aluminum hydroxide the recited SP oil adjuvant in a buffered salt solution. The prior art cited by the Examiner fails to show a vaccination with a vaccine comprising *E. coli* O157:H7 with either of SP or aluminum hydroxide. Johnson, the primary reference relied upon by the Examiner and the only cited reference that even mentions *E. coli* O157:H7, discloses vaccination without any adjuvant. In comparing the claimed invention combining *E. coli* O157:H7, SP oil and aluminum hydroxide to compositions comprising *E. coli* O157:H7 and aluminum hydroxide, the Li Declaration shows unexpected results of the claimed invention to a composition that is closer than the prior art cited by the Examiner. No more is required. It is thus legal error for the Examiner to find the Li Declaration "insufficient because the adjuvant compared in the declaration is vastly different than metabolizable oil adjuvants or 'SP Oil' *as claimed.*" Final Office Action date January 7, 2009 at page 4 (italics added). The Examiner has improperly required the Applicants to show unexpected results by comparing the claimed invention to itself and consequently erred in failing to give due consideration to the unexpected results reported in the Li Declaration. The Li Declaration, in fact, shows that the claimed invention provides unexpected results over the prior art. For this additional reason the rejections should be withdrawn.

3. The Examiner Has Failed to Provide a Legitimate Rationale for a Reasonable Expectation for Success in Combining the Prior Art to Arrive at the Claimed Invention

The Examiner's failure to properly consider the scope and content of the prior art results in an improper rationale for combining the prior art to arrive at the claimed invention. The Examiner thus asserts that:

> It would have been expected, barring evidence to the contrary, that the composition would be effective in reducing shedding of *E. coli* O157:H7 because all the claimed elements were known in the prior art

> and one skilled in the art could have combined the elements with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.
>
> Final Office Action dated January 7, 2009 at page 8.

The Examiner's rationale is misplaced on a number of fronts. First, Johnson reports that a vaccine comprising *E. coli* O157:H7 did not have a significant effect on shedding of bacteria. Thus Johnson provides explicit "evidence to the contrary" that, at the time the invention was made, one of ordinary skill in the art would have a reasonable expectation that the claimed composition would be effective in reducing shedding of *E. coli* O157:H7. Additionally, both Saito and Baylor disclose explicitly that vaccines comprising aluminum hydroxide are known to cause lesions at the injection site. Thus, contrary to the Examiner's assertion, the claimed combination leads to a change in the "function" of aluminum hydroxide by reducing injection-site lesions and it would not be predictable that the claimed combination could predictably lead to such a result.

4. The Examiner Has Used the Applicants' Claims and Hindsight Reconstruction as Motivation to Combine the Prior Art

It is axiomatic that the Examiner may "not use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *In re Fritch,* 972 F.2d 1260, 1266 (Fed. Cir. 1992) (internal citations omitted). It is improper, in determining whether a person of ordinary skill would have been led by the combination of references, simply to "[use] that which the inventor taught against its teacher." *In re Lee,* 277 F.3d 1338, 1343 (Fed. Cir. 2002), *citing W.L. Gore v. Garlock, Inc.,* 721 F.2d 1540, 1553 (Fed. Cir. 1988) ("[t]here must be a reason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicant's disclosure").

In KSR, the Supreme Court cautioned that "[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of argument reliant upon ex post reasoning." *KSR,* 550 U.S. at 421 (*citing Graham v. John Deere Co.,* 383 U.S. 1, 36 (1966)). "[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l. Co. v. Teleflex Inc.,* 550 U.S. 398,

418 (2007), *quoting In re Kahn,* 441 F.3d 977, 988 (Fed. Cir. 2006). "'[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *Id.* The Court stated:

> [I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does . . . because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

Id. at 418-419; *see also id.* at 418 (requiring a determination of "whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue").

Here, the Examiner has failed to correctly identify any reason why one of ordinary skill in the art would combine elements of the prior art to arrive at the claimed invention. The Examiner relies on a selective reading of the prior art to arrive at the unsupported conclusion that as "one skilled in the art could have combined the elements with no change in their respective functions, and the combination would have yielded predictable results." The lack of support for such a conclusions it is clear the Examiner has used the instant specification as a blueprint for the rationale combine the prior art to arrive the instant claims. Such hindsight reconstruction is improper. For this reason additionally, the obviousness rejection based on Johnson in view of Saito and Baylor should be withdrawn.

(2) RESPONSE TO GROUND 2: CLAIMS 22-24 ARE PATENTABLE UNDER 35 U.S.C. 103(A) OVER JOHNSON IN VIEW OF SAITO, BAYLOR AND ELDER

Section (1) set forth above is hereby incorporated herein by reference. Claims 22-24 are rejected as obvious over Johnson in view Saito, Baylor, and Elder. The Examiner's rejection of claims 22 and 24 as set forth in the instant rejection relies on the combination of Johnson, Saito and Baylor, applied as discussed above. *See,* e.g., Final Office Action mailed January 7, 2009 at page

10, bottom paragraph. The Examiner relies on Elder as disclosing administration of neomycin to reduce fecal shedding of E. coli O157:H7 and applies Elder only in the rejection of claim 23 (which is directed to the method of claim 22 further comprising administering an effective amount of Lactobacillus acidophilus or neomycin medicated feed supplement to the animal). Final Office Action mailed January 7, 2009 at page 11, bottom paragraph et seq.

For all of the reasons set forth above, claims 22 and 24 are patentable over Johnson in view of Saito and Baylor. Because the Examiner does not cite Elder in connection with claims 22 and 24 and Elder does not, in fact, cure any of the defects set out above in Section (1) concerning the rejection of claims 22 and 24 over Johnson, Saito and Baylor, it follows that claims 22 and 24 are not obvious over Johnson in view of Saito, Baylor and Elder.

Claim 23 depends from independent claim 22. Claim 23 thus includes all of the limitations and further limits claim 22. It is thus axiomatic that if an independent claim is not obvious, all dependent claims that rely on the independent claim as a base claim are also not obvious. Accordingly, because claim 22 is not obvious over Johnson in view of Saito, Baylor and Elder it follows that claim 23 is also not obvious over Johnson in view of Saito, Baylor and Elder.

For the reasons set out above, claims 22-24 are not obvious over Johnson in view of Saito, Baylor and Elder.

* * *

CONCLUSION

For the reasons set forth above, Appellant requests that the Board reverse the rejections of claims 22-24.

Dated: December 10, 2009

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